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I HEREBY CERTIFY that annexed hereto is a true copy of
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application:

JUL 29 2002

OFFICE OF PETITIONS

Application No. 950950

Date of Filing 18 December 1995

Applicant ALLIANCE INVESTMENTS LIMITED, an Irish
Company of Monksland Industrial Estate, Athlone,
County Westmeath, Ireland.

Dated this 24 day of May 2002.

Carey

An officer authorised by the
Controller of Patents, Designs and Trademarks.

950950
FORM NO. 1

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT 1992

The Applicant(s) named herein hereby request(s)

[X] the grant of a patent under Part II of the Act
[] the grant of a short-term patent under Part III of the
Act
on the basis of the information furnished hereunder.

1. Applicant(s)

ALLIANCE INVESTMENTS LIMITED,
Monksland Industrial Estate
Athlone
County Westmeath
Ireland
an Irish Company

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2. Title of Invention

A therapeutic device

3. Declaration of Priority on basis of previously filed
application(s) for same invention (Sections 25 & 26)

<u>Previous Filing Date</u>	<u>Country in or for which filed</u>	<u>Filing No.</u>
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4. Identification of Inventor(s)

Name(s) and addressee(s) of person(s) believed
by the Applicant(s) to be the inventor(s)

Patrick J Connolly
Lissoy, The Pigeons, Athlone, County Westmeath, Ireland

5. Statement of right to be granted a patent (Section 17(2) (b))

The Applicant derives the right to apply by virtue of a Deed of Assignment dated: December 6 1995

6. Items accompanying this Request

- (i) prescribed filing fee (IRP 117)
- (ii) specification containing a description and claims
 specification containing a description only
 Drawings referred to in description or claims
- (iii) An abstract
- (iv) Copy of previous application(s) whose priority is claimed
- (v) Translation of previous application whose priority is claimed
- (vi) Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. Divisional Application(s)

The following information is applicable to the present application which is made under Section 24 -

Earlier Application No.

Filing Date:

8. Agent

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted -

Name & Address

Cruickshank & Co. at their address recorded for the time being in the register of Patent Agents is hereby appointed Agents and address for service, presently 1 Holles Street, Dublin 2.

9. Address for service (if different from that at 8)

Signed Cruickshank & Co.

By:-

Executive.

Agents for the Applicant

Date 18/12/1995

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950050

APPLICATION NO.

- 1 -

"A Therapeutic Device"

Description

The invention relates to a device for rotating a patient from the supine position to the prone position and the reverse, if necessary alternating, by an angle lying between the two.

During the medical care of patients who are unable to move, it is frequently necessary to move the patient rapidly from the back prone position into the frontal prone position or into a titled position between these positions, in order to carry out examinations or treatment to relieve the pressure on certain organs. One therapy, which is successfully used in particular with accident victims or patients having limited lung functions, consists of interchanging the loading of the two sides of the lung by alternately rotating the patient from the back prone position to both sides by a tilt angle of 15 - 62 degrees. Any fluid collected in the lung is transferred alternately from one side of the lung to the other by virtue of this so-called kinetic therapy, which functions by gravitational force. The function of the lung is improved. Although therapeutic beds which render it possible to carry out these continuous tilt movements are already in use, they are not equipped to rotate the patient about 180 degrees, i.e. from the back prone position to the frontal prone position and vice-versa.

According to most recent finding, it is often not possible using mechanical ventilating machines alone to compensate serious oxygen deficiency (ARDS = Adult Respiratory Distress Syndrome) caused by acute damage to the lungs and which frequently occurs as a part of a sepsis syndrome.

The effects of a mechanically supported ventilating system, which can be described as a simultaneous mixture of spontaneous breathing with a time-controlled, pressure-limited artificial respiration, is however considerable
5 improved by a kinetic therapy with intermittent frontal prone position - F. Hiltenkamp et al., "Kinetische Therapie und Bauchlage bei Patienten mit ARDS und Biphasic Positive Airway Pressure Beatmung" in "intensiv" [Kinetic therapy and frontal prone position of patients with ARDS
10 and biphasic positive airway pressure artificial respiration] (Technical periodical for intensive care and anaesthetics), 2nd issue, May 1994, Pages 50 - 56.

Whereas therapeutic beds which can be tilted up to 62 degrees can be used for kinetic therapy, only simple pivot
15 or tilt beds are available to rotate the patient into the frontal prone position, wherein it is necessary to clamp the patient in place between two mattress frames prior to the rotational movement and at least 2 - 3 persons are required to carry out the rotational movement (DE-OS 27 11
20 153 and R. Birkenfeld, "Oberwachung und Pflege des beatmeten Patienten" [Monitoring and care of patients being ventilated, Publishers Bustav Fischer, Sututtagardt, New York 1988, Pages 130 - 133.)

Although this is an advancement on the rotational movement
25 carried out by nursing staff, which required four to five people, it does not meet modern demands owing to the inaccessibility of the patient who is held in place under pressure and without lateral securing means. Such sandwich type beds are not suitable for kinetic therapy or
30 even for kinetic therapy with intermittent frontal prone positioning in which the patient remains on his/her stomach for approximately 6 - 10 hours and is then generally rotated for some into the back prone position . In addition to these disadvantages, the known pivot or

tilt beds do not allow for supply lines for oxygen, infusion etc, which are connected to the patient, to be rapidly rotated in a controlled manner, which can be critical where resuscitation measures are required for patients lying in the frontal prone position.

The invention overcomes all these disadvantages and inadequacies by virtue of the construction defined in the claims together with their preferred embodiments.

The important part of the device in accordance with the invention, i.e. a hospital bed for the purpose of rotating patients who require kinetic therapy and/or to be positioned for longer or intermittent periods in the frontal prone position, resides in a drum which can be rotated and fixed as desired on support rollers, furthermore in the rotational member for the purpose of receiving the patient in the rotational axis from half-shells which can be released from each other rapidly and thus allow full and immediate access to the patient. The half-shells correspond to the contour of the patient and comprise on all sides soft supporting bearing surfaces for the back, side and front. The geometry of the drum permits the optimum accessibility to the patient and supply lines which are guided in a controlled manner during the rotating process.

It is advantageous that the device can be assembled to conventional hospital beds as outlined in claim 2.

The rotational member and the carrier frame comprising a flat or profiled member for the support rollers can be made from metal or reinforced synthetic material, for example from glass fibre-reinforced polyester material. The support rollers consist preferably of steel and can be surface-coated with gum or otherwise rendered anti-slip.

In order to support the rotational member in a secure manner during the tilt process, a single longer or two separate, shorter roller pairs can be disposed at sufficient spaced disposition with respect to each other

5 (Claim 3).

Known plug-in connections serve to join together the half-shells of the rotational member. The said connections can be moulded either in the longitudinal edges whilst maintaining a smooth drum surface (Claim 4) or, if pairs of parallel rollers are used at a spaced disposition as a support, they can sit on the rotational member periphery protruding within this spacing (for example a pin bolt having a tubular counter piece).

When using an automatic drive unit, which facilitates kinetic therapy as described above and/or the intermittent frontal prone position, the force can be transmitted to at least one of the bearer rollers or rather its shaft by means of flat, wedge-shaped or toothed belts (Claim 9) but also by means of a chain drive or toothed wheel drive.

20 The drive roller and rotational member can be connected in a non-positive manner by means of a toothed wheel/toothed ring unit (Claim 10). An alternative is to use a coating which improves the adhesive properties on the drive roller and on the peripheral portion of the rotational member 25 which cooperates therewith.

Instead of the spring bold locking mechanism according to Claim 10, it is also possible to use a brake shore which can be pressed by means of a threaded spindle against the rotational member periphery or its end face defining the 30 cylindrical portion.

The padding of the two half-shells can be extremely simplified in that the means a) - d) of Claim 12 can be replaced fully or partially, as stated in Claim 13, by a combination of corresponding air-cushions, which can be released if necessary and which have surfaces of different hardness. The air-cushions can for this purpose be provided with inner support ribs which have a different tensioning force and the said air-cushions can be inflated separately. The combination which consists of a plurality of air-chambers which are attached to each other or of one unit comprising a plurality of air-chambers renders it possible to position the patient particularly rapidly and reliably in the most varied space requirements.

The embodiments of the device in accordance with Claims 14 and 15 can be further improved by virtue of the fact that perforated face shells, which can be inserted into the supply orifice of the half shell for the frontal prone position and which face shells have various sized support surfaces for the facial areas of larger and smaller patients, are provided in such a manner that they can be replaced.

A preferred embodiment of the invention is explained below with reference to the drawings, in which:

Fig. 1 shows a lateral view of the device attached to a hospital bed;

Fig. 2 shows a view of the front end of the cylindrical portion of the device as shown in Fig. 1;

Fig. 3 shows a plan view of the device as shown in Fig. 1;

Figs. 4 and 5 show a longitudinal sectional view through the rotational member with padding with a patient in different positions.

The embodiment as shown in Fig. 1 and 2 consists of a drum-shaped container, the rotational member 1. The rotational member consists of two half-shells 4, 4'. The half-shells 4, 4' are attached at their longitudinal edges formed as a groove/resilient plug-in connection 12 and connected to each other by means of Velcro fasteners 13. The rotational member comprises a cylindrical portion 5 and a truncated cone-shaped portion 6. The latter comprises in the half shell 4', which is located above when positioning the patient into the back prone position, a supply orifice 8 in the face region of the patient rendering it possible for the doctor to manipulate the air passages, observe the eye reaction and to provide artificial respiration with oxygen etc. The rotational member 1 is provided on its ends about its rotational axis 1' with circular orifices 7, through which lines for monitoring devices etc. can be introduced.

Each of the half-shells comprises a padding 9 for the purpose of fixing the position of the patient in a comfortable manner during the rotational movement, in particular about 80 degrees. Loops 17 are provided on the periphery or rather at the foot-side end face of the rotational member in order to be able to rotate manually the patient from the back prone position into the frontal prone position and the reverse.

Rotatable rollers 2 which are disposed at a lateral spaced disposition with respect to each other form the support for the rotational member 1 and the longitudinal axes of the said rollers are directed parallel to the rotational axis 1' of the rotational member. The rollers are

provided here as a front and rear roller pair. The roller pairs support the rotational member in its cylindrical portion (see Fig.3).

Each of the said roller pairs is received with its shafts
5 14 bearing blocks 15, which are attached in each case on
a frame-shaped front and rear carrier 3' or 3" (see
Fig.3). The diameter of the rollers and the height of the
bearing arrangement are dimensioned such that the
rotational member has sufficient ground clearance with
10 respect to the carrier frame.

Furthermore, stop means 16 are provided on the two carrier frames for the purpose of preventing axial movement of the rotational member.

The carrier frame 3 is placed on the frame of a
15 conventional hospital bed 10 and clamped thereto by means
of screw clamps 11 attached to the longitudinal limbs of
the carrier, which screw clamps are formed in such a
manner as to be able to pivot in a manner known per se for
the purpose of engaging below the bed frame. (see the
20 schematic illustration in Fig. 2).

A drive unit 18, which consists of an electric motor and control means, is attached in the rear region of the device at the lower side of the carrier frame 3 for the rear bearer rollers 2, which drive unit influences one of
25 the two rear rollers by means of a belt drive. The control means of the motor is designed in a manner known per se such that it allows any rotational movement of the rotational member 1, i.e. also alternating tilt movement of the patient by any angle.

30 In the event that a predetermined tilt position of the patient is indicated, then the rotational member can be

locked in this position by means of a locking device, which, as shown in Fig.12, consists of bore holes 19 provided at angular spacings of 15 degrees respectively in the outer region of the rear end face of the rotational member pin arrangement 21 sits on a bracket 20 attached to the carrier 3 and comprises a spring pin having a draw head 21 of a construction known per se, which spring pin can be locked in this tensioned state and when relaxed engages in one of the bore holes 19.

10 Figs. 4 and 5 show a convenient embodiment of the half-shell padding 9, which consists of a coating of HR-foam plates 22 on each of the half-shells or - alternately - an inflatable air-cushion 25, a mattress 23 and a profiled foam block sides of the patient. When the half-shells are
15 joined together, the said elastic cushions fill the space between the lateral portions of the profiled foam blocks (not illustrated). Each of these two cushions is convex on the drum side and concave on the patient side.

20 Fig. 5 shows that, owing to the requirements that the supply orifice 8 remains uncovered in the front, i.e. head side portion, the half-shell 4' for the frontal prone position cannot be padded in an identical manner as the half-shell 4 for the back prone position. On the contrary, the layers 22 (25), 23 and 24 terminate here at
25 the beginning of the supply orifice 8 and the support for the forehead and front of the head is provided by a profiled foam block 26 disposed in the space of portion 6 after said orifice, which profiled foam block 26 is approximately the shape of a "deformed half-cone."

30 The device functions as follows:

If the half-shell 4' is removed, the half-shell 4 is rotated in such a manner that its longitudinal edges and the padding lie in the horizontal plane and are locked to prevent rotation. The patient is then moved into the back
5 prone position with his/her face in portion 6 and the lateral wedge-shaped cushions are pushed in. Once locked into place, the bd can then be rotated into a required inclined position.

As a result of the patient being arranged substantially in
10 the rotational axis 1', the force of one person is sufficient to rotate the bed by any desired angle. If an alternating tilt movement is desired, e.g. by an angle of 15 - 62 degrees, then this can be performed mechanically and automatically by way of the drive unit 18.

15 If it is necessary to rotate the patient into the frontal prone position, then the half-shell 4' is placed on the half-shell 4 and connected by means of the Velcro fasteners 13. The patient is supported purposefully on all sides with moderate pressure by virtue of inflating
20 air-cushions 25 and by virtue of the side cushions, while his/her face remains uncovered in the region 8. The drum can now be rotated about 180 degrees by means of the loops 17 or mechanically and locked again.

If the patient is to remain for a longer period in the
25 frontal prone position, then his/her head is supported by means of a face shell, which is inserted into the supply orifice 8 and clamped in place therein (see Claim 17). The face shell can either support only the face periphery or additional parts of the face, in which case the part of
30 the face shell towards the face is then perforated.

In an emergency, e.g., if resuscitation is required, the patient can likewise be moved back rapidly into the back

prone position. Once the half-shell 4' has been removed, the patient is ready to receive the treatment.

The supply orifice 8 and the recess 7 lie in the proximity of or rather directly in the rotational axis of the drum.
5 The lines for artificial respiration, intravenous infiltration, ECG, compressed air for the air-cushions etc. which are guided through these orifices can therefore be rotated at the same time in a controlled state.

10 The device provides a decisive improvement of the survival changes of problematic patients, since they can be both tilted as desired and also rotated about 180 degrees in one and the same bed, which for the first time allows the use of a combination of kinetic therapy with the
15 intermittent frontal prone position without the patient having to be moved to a different bed. In addition, the device can be operated easily by a single person.

The invention is not limited to the embodiments hereinbefore described which may be varied in both construction and detail.
20

LIST OF PARTS

1. Hospital bed.
2. Half-shell for receiving the patient in the back prone position (e.g. from GFK).
- 5 3. Half-shell for receiving the patient in the frontal prone position.
- 10 4. Front support having two rotatably mounted rollers and stopping angles for fixing the roller in the axial direction (consisting of half-shell 2 + 3) towards the front (head end).
- 15 5. Rear support having two rotatably mounted rollers and stopping angles for fixing the roller in the axial direction towards the rear (foot end). (The brackets 4 and 5 are clamped in place on the bed frame by virtue of wing screws or clamping levers).
- 20 6. Velcro or clamp fasteners for connecting the two half-shells in addition 7.
7. Groove and resilient plug-in connection for connecting the two half-shells.
- 20 8. Handles and loops for rotating the roller by hand and for removing the upper lying half-shell.
9. Orifice over the face for supply purposes to the patient (tubes, hoses, etc.).
- 25 10. Orifices in the rotational axis of the roller for anything else.

11. Locking the roller by means of the spring pin having a draw head.
12. Bore holes at the periphery of the roller (e.g. all 15 degrees) for locking the roller in any position, 5 in particular for a rotation about 180 degrees into the frontal prone position.
13. Electrical drive (e.g. by means of belts which influence a roller of the rear support 5), having a control unit for the purpose of automatically rotating the patient into the frontal prone position, 10 but also for the purpose of providing kinetic therapy (rotating to and fro into predetermined inclined positions).
14. Fixed base, adapted to the "height" of the patient by placing on HR-foam plates of different thicknesses, 15 alternately, variable base, adjusted by supports of different heights in the half-shell and by inflating air-cushions below the base.
15. Mattress.
- 20 16. Profiled foam, which corresponds to the body
 - for the purpose of supporting the patient without any pressure loading
 - for the purpose of fixing the patient in a non-slip manner during the rotational movement.
- 25 17. Conical design at the head end of the roller for the purpose of fixing the head, in addition a face shell integrated in the half-shell for the frontal prone position.

18. Various wedges for the purpose of fixing the side of the patient during the rotational movement (in various sizes depending upon the size and weight of the patient).

CLAIMS

1. Device for rotating a horizontal patient from the supine position into the prone position and the reverse or, if necessary alternating, by an angle value between the two positions, characterised by a support for a hollow rotational member comprising a circular cross-section (1) for the purpose of receiving the patient substantially in the rotational axis (1'), consisting of at least two rotatable rollers (2) which are disposed parallel to each other and to the rotational member and at a spaced disposition with respect to each other and the bearing arrangement of the said rollers is attached to a frame-shaped carrier (3) which is if necessary connected to a sub-frame, and furthermore characterised by the rotational member (1) formed from two symmetrical half-shells (4,4') which lie on the rollers (2) and which can be combined to form one stable unit, which rotational member consists of a cylindrical portion (5) for the lower body of the patient and a truncated cone-shaped portion (6) for the purpose of receiving the upper body and head, wherein the end face of each of the portions is closed or comprises a circular opening (7) about the rotational axis (1'), the periphery of the portion (6) comprises a supply orifice (8) in the half-shell (4') concealing the face area of the patient and both half-shells comprise a padding (9) which rests against the contour of the patient and characterised in that the maximum length of the rollers (2) is equal to the length of the portion (5) and their transverse spacing and their crown height above the carrier (3) ensures that there is sufficient ground clearance to rotate the rotational body and that the rotational body lies in a stable manner.

2. Device according to claim 1, characterised in that
the carrier (3) is in the form of a fixture for a
conventional hospital bed (10) and arrangements of
clamping livers are attached for the purpose of
connecting the fixture and the bed to the
longitudinal limbs of the carrier or pivotable screw
clamps (11) are attached for the purpose of engaging
below the bed frame.
3. Device according to claim 1 or 2, characterised in
that the support for the rotational member is in two
parts and a front and a rear pair of rollers (2) is
disposed on a common carrier or on separate carriers
(3',3") respectively.
4. Device according to claims 1 to 3 , characterised in
that the longitudinal edges of the half-shells are in
the form of a groove/resilient plug-in connection
(12).
5. Device according to claims 1 to 4, characterised in
that in order to connect the two half-shells in a
stable manner Velcro fasteners or clamping fasteners
(13) are provided in the region of their longitudinal
edges, which fasteners engage over the said edges.
6. Device according to claims 1 to 5, characterised in
that the shafts (14) of the rollers (2) are received
in bearing blocks (15) attached to the carrier (3),
which bearing blocks are formed int he region of the
planes defining the portion (5) as stopping means
(16) for the rotational member to prevent axial
displacement or said bearing blocks support such a
stopping means.

7. Device according to claims 1 to 6, characterised in
that grips or loops (17) are provided on the
periphery of the rotational member, preferably in the
region of the portion (6) and the end face of the
portion (5), in order to be able to carry out the
rotational movement by hand and for the purpose of
removing the respective upper-lying half-shell.
5
8. Device according to claims 1 to 6, characterised in
that a circumferential railing is provided on the end
face of the portion (5) of the rotational member in
order to be able to rotate the said rotational member
by hand.
10
9. Device according to claims 1 to 8, characterised in
that a drive unit (18) consisting of an electric
motor and control means is provided on the lower side
15 of the carrier (3) in the region of the end face of
the portion (5) and the said drive unit is connected
by way of a belt drive to at least one of the support
rollers or rather the shaft thereof.
- 20 10. Device according to claim 9, characterised in that
the driven support roller is formed at least in one
part of its length as a toothed wheel, which is
connected in a non-positive manner to a two-part
toothed ring which extends in the region of the
25 toothed wheel in a closed manner over the periphery
of the supported rotational member (10 and is
attached to the half-shell (4, 4') thereof.
- 30 11. Device according to claims 1 to 10, characterised in
that for the purpose of locking the rotational member
in any position bore holes (19) are provided,
preferably in angular spacing of 15 degrees
respectively, in the outer region of the end face of

the portion (5) and - corresponding thereto - a spring bolt can be locked in a tensioned state and in a relaxed state engages in one of the bore holes.

- 5 12. Device according to claims 1 to 11, characterised in
 that the padding (9) of the half-shell (4) comprises
 a plurality of layers and - from the inside towards
 the outside - consists of:
- 10 a) one or a plurality of HR-foam plates (22) in
 order to be able to adjust the level,
- c) a mattress (23),
- d) on each side of the patient fixing wedges which can
 be inserted or profiled supports.
- 15 13. Device according to claim 12, characterised in that
 the layer (a) is replaced by an inflatable air-
 cushion made from an elastic material (25).
- 20 14. Device according to claim 12 or 13, characterised in
 that a recess for the rear of the head of the patient
 is provided in the profiled foam block c) of the
 half-shell (4).
- 25 15. Device according to claims 1 to 13, characterised in
 that the padding (9) of the half-shell (4') is
 constructed as indicated in claims 12 and 13, but
 extends only as far as the supply orifice (8) and a
 semi-conical profiled foam block (26) is disposed in
 the area of portion (6) after the supply orifice for
 the purpose of supporting the forehead and the front
 of the head.

16. Device according to claim 15, characterised in that a recess for the feet is provided in the profiled foam block c) of the half-shell (4').
- 5 17. Device according to claim 15 or 16, characterised in that the face shell sits in the supply orifice (8) of the half-shell (4') in such a manner that it can be inserted in a clamped manner and can be replaced, which face shell supports the periphery of the face (forehead, cheeks and chin) yet leaves free the eyes, 10 nose, mouth and neck region.
18. Device according to claim 17, characterised in that the face shells comprise supporting contours for large and small patients.
- 15 19. A device substantially as hereinbefore described with reference to the accompanying drawings.

CRUICKSHANK & CO.,

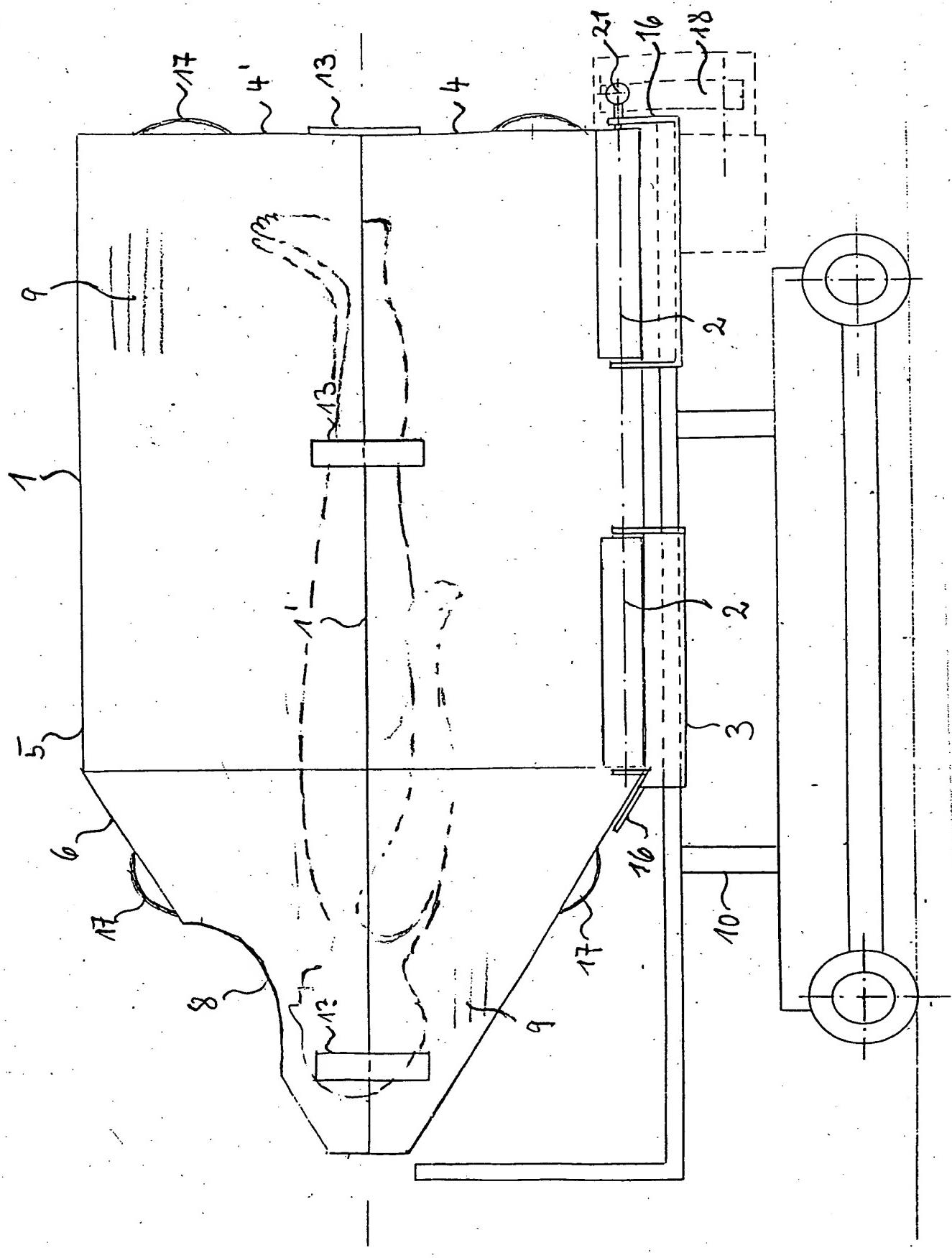


Fig. 1

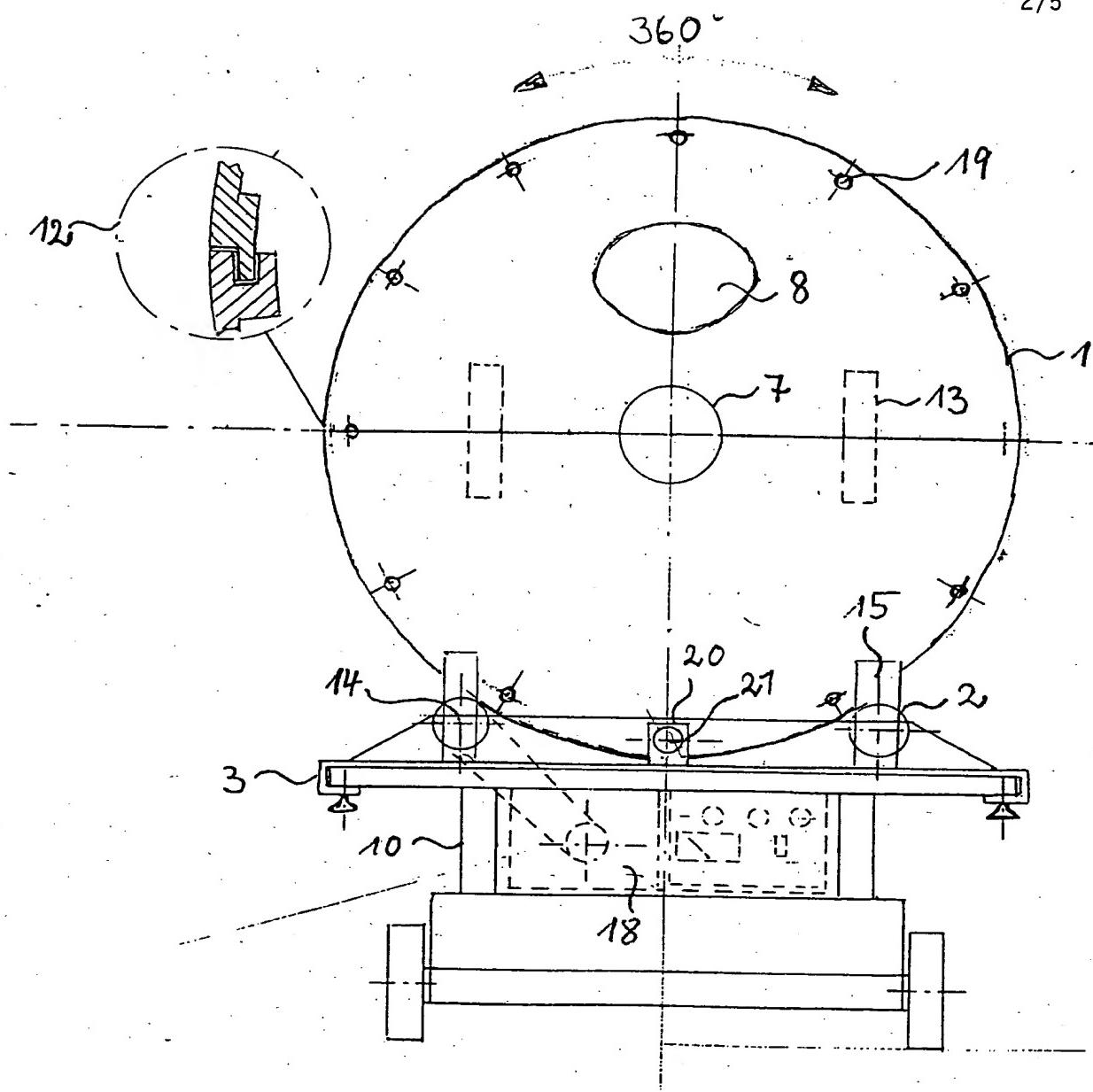


Fig. 2

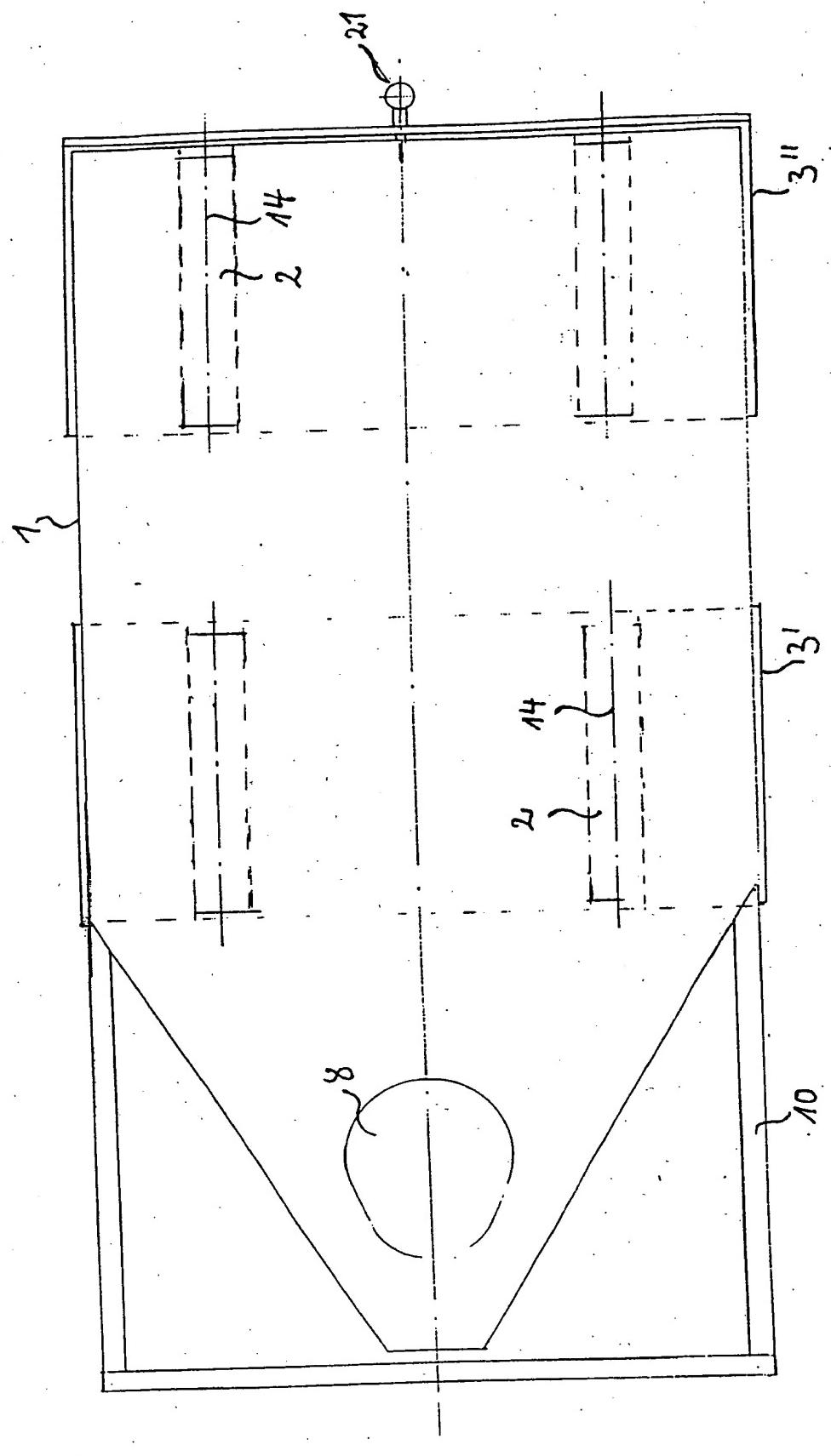


Fig. 3

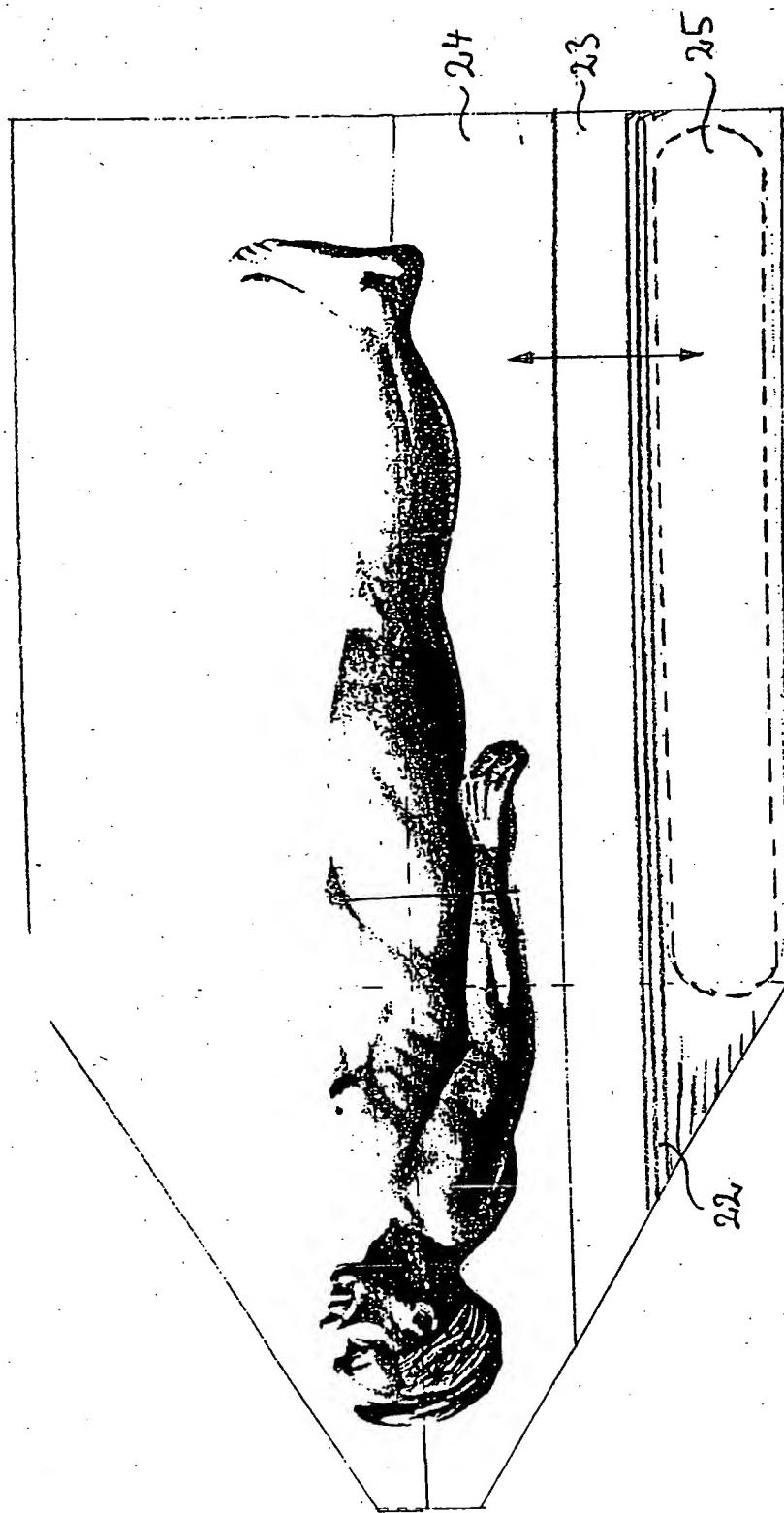


Fig. 4

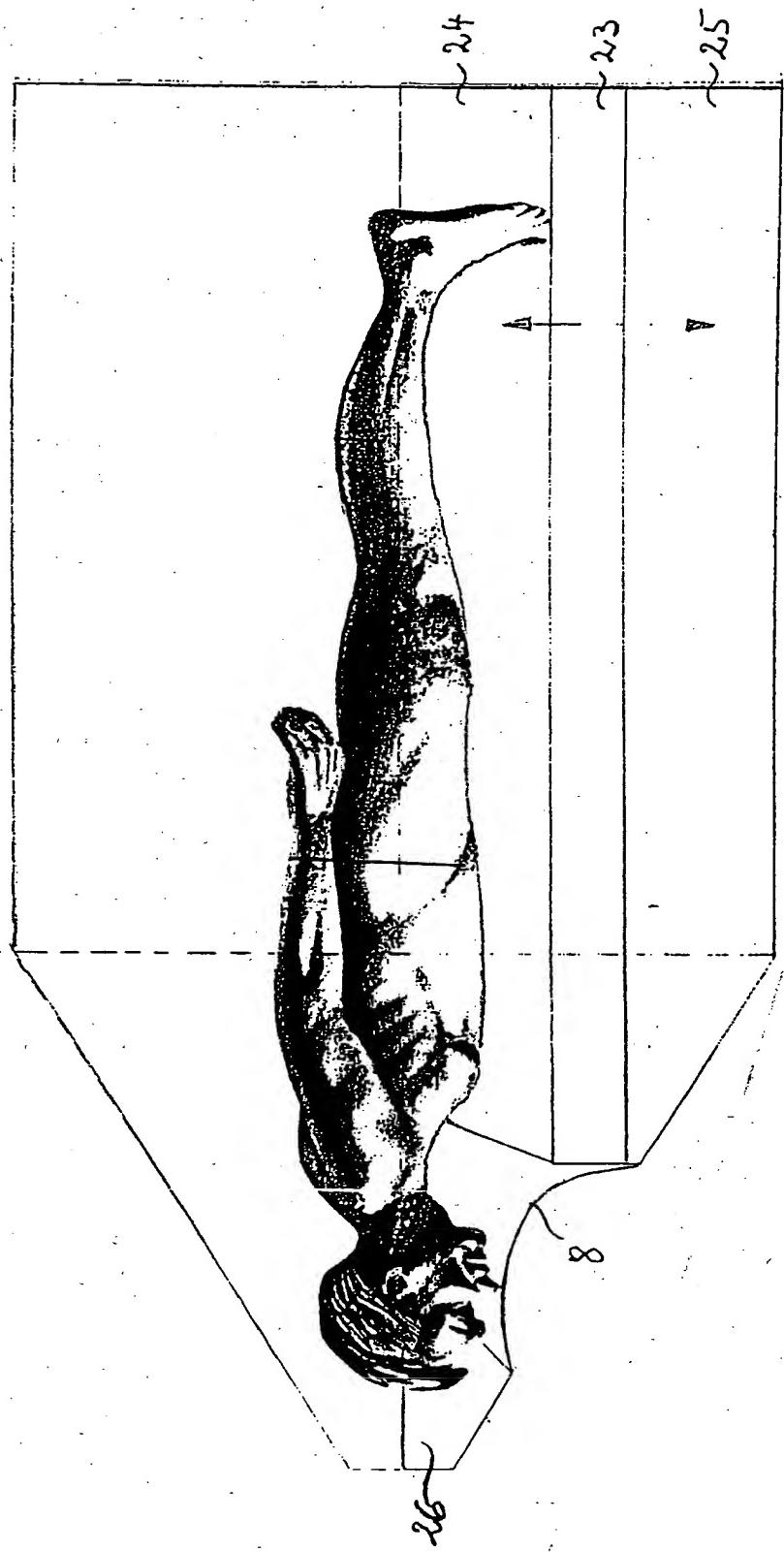


Fig. 5